

Dutch Accreditation Council (RvA)

Policy rule for Cross-Border Accreditation

Document code: RvA-BR007-UK

Version valid from: 17-05-2023



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1. Introduction

Article 1.

This document sets out the RvA policy for the accreditation and assessment of Conformity Assessment Bodies (CABs) registered and/or acting outside the Netherlands, for the assessment of CABs in the Netherlands on request of other Accreditation bodies (ABs) and for the accreditation and assessment of CABs for foreign national regulation.

The policy is based on Regulation (EC) No 765/2008, the EA cross-frontier policy document EA-2/13 and relevant rules and guidance or mandatory documents from ILAC and IAF.

Article 2.

The purpose of this policy rule is to support one-stop accreditation and one-stop conformity assessment principles. It is also designed to maintain a level playing field for CABs accredited by the RvA and those accredited by other EA-MLA, IAF-MLA and ILAC-MRA partners. The policy rule also aims to ensure a consistent and non-discriminatory approach in dealing with the accreditations or applications of bodies in different countries.

Article 3.

This policy rule applies to accreditation and assessments of:

- 1. CABs with a head office outside the Netherlands;
- CABs with a head office in the Netherlands that also perform conformity assessment activities in other countries;
- 3. CABs in the Netherlands acting as a site of a foreign CAB accredited by a foreign AB;
- 4. CABs in the Netherlands performing conformity assessment activities for a foreign national regulation;
- 5. Foreign CABs accredited by a foreign AB for which cooperation with the RvA is requested.

Article 4.

This policy rule distinguish between accreditation and assessments within the EA-MLA region and accreditation and assessments outside this region. The EA-MLA region includes all countries with an AB that is signatory of the EA-MLA or of the Bilateral agreement with EA (EA-BLA).

Article 5.

This policy rule will come into force on 17 May 2023.

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2. RvA general policy on cross border accreditation and assessments

Article 6.

It is the primary task of RvA to service CABs in the Netherlands. Any decision to provide accreditation or assessment services in other countries will be made taking this task into account.

Article 7.

When requested to provide accreditation to a CAB outside the Netherlands, or to conduct assessments for Dutch CABs outside the Netherlands, and/or to conduct assessments for Dutch CABs against foreign national regulation, RvA will apply the following general policies:

- RvA will only provide accreditation and assessment services outside the Netherlands in case this
 will contribute to the international development and harmonisation of accreditation and conformity
 assessment.
- 2. RvA will not compete with other ABs.
- RvA will not provide its services in countries for which the difference between the values and culture in that country and the Dutch values and cultures makes it impossible to conduct reliable assessments; to be decided and motivated by the RvA Executive Board.
- 4. RvA will not provide its services in countries where the safety of its staff is not guaranteed. The travel advice from the Dutch Ministry of Foreign Affairs will be leading for such a decision.
- 5. RvA will not provide its services outside the Netherlands if, based on the available resources, this would have a negative impact on its capacity to provide its services in the Netherlands.
- 6. The costs associated with cross border accreditation and assessments, including the costs for translation of documents, use of interpreters and coordination of assessments with other ABs will be invoiced to the RvA accredited CAB or the CAB requesting RvA accreditation or to the foreign AB requesting cooperation from RvA.
- 7. RvA will only provide accreditation outside the Netherlands for activities for which it has obtained sufficient experience in the Netherlands and for which the policy rule RvA-BR010 states that activities may also be accredited outside the Netherlands.

Article 8.

In the case of accreditation for foreign national regulation, the RvA will contact the NAB of the country issuing the regulation. With the use of local experts, the RvA will gather the necessary knowledge of and information on the regulation.

Article 9.

Whenever cooperation is requested by a foreign AB, the RvA will make an effort to establish an effective cooperation and respond, if possible, in accordance with the request made by the foreign AB.

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3. RvA accreditation and assessments in the EA-MLA region

Article 10.

For accreditation within the EA-MLA region the RvA applies the principles stated in Regulation (EC) No 765/2008. The RvA policy is:

- 1. The RvA does not grant accreditation to CABs in other countries within the EA-MLA region. Exceptions to this policy are those situations where Article 7, paragraph 1 of the Regulation (EC) 765/2008 applies, meaning that a member state has not appointed a NAB, the NAB does not perform accreditation of the respective activities or the NAB is not an EA-MLA signatory for the respective activities. In these situations the RvA will conduct the assessments, and where applicable and possible involve the respective NAB.
- 2. If an exception based on Article 7, paragraph 1 of the Regulation (EC) 765/2008 stops to apply, the RvA will not initiate a new accreditation cycle or extend an accreditation. In these cases, the RvA will confirm to CAB's involved that no new accreditation cycle will be scheduled. At the request of the CAB, the RvA will provide the necessary information on relevant assessments during the last accreditation cycle to any other NAB, to facilitate the process of obtaining a new accreditation.
- 3. Where the NAB has become a signatory of the EA-MLA or EA-BLA or has started performing accreditation for the specific activities after the RvA has granted accreditation to a CAB in this country, the RvA will support the transfer of the accreditation to the NAB before renewal where possible and if requested by the CAB.
- 4. Also when other grounds for providing cross border accreditation to a CAB in the EA-MLA region have changed and also at the occasion of each re-assessment and requests of scope extensions, the RvA will confirm that previously accepted justifications and conditions for providing cross border accreditation still apply.
- 5. If the RvA is going to accredit a CAB in another country in de EA region, it shall inform the NAB of this country of its intentions and keep it informed of its actions.
- 6. In case the RvA is not able to establish cooperation with a NAB within the EU region in accordance with the EA procedures, the RvA will keep records of the reason why this cooperation could not be established.

Article 11.

Assessments of foreign sites of Dutch RvA accredited CABs will be subcontracted to the NAB, in which case <u>chapter 7</u> applies.

Article 12.

The witnessing of activities outside the Netherlands (for example on-site testing, audits, inspections) that Dutch CABs conduct within the EA-MLA region, will be subcontracted to the NAB of the country where the activities take place.

Article 13.

The frequency and extent of the assessments of sites where one or more key activities are carried out (see RvA-BR003 for the definition of key activities) in other countries in the EA-MLA region is decided based on the following principles:

- In case the foreign site is accredited by the NAB for the same scope, then the frequency and
 extent according to the NAB's policy will be applicable. The assessments subcontracted by RvA
 are considered to be part of the NAB's assessments.
- 2. In situations referred to in the first paragraph RvA may decide with reasons to have additional assessment activities, subcontracted to the NAB.
- 3. In case the foreign site is accredited by the NAB but this accreditation does not cover the RvA's scope of accreditation, then for the common parts of the scope <u>paragraphs 1</u> and <u>2</u> apply. For assessments of the scope parts that are additional to the NAB's scope the frequency of RvA's policy (RvA-BR005) will be applied. The assessments subcontracted by RvA may be conducted during the NAB's assessments, but additional assessments may be required also.
- 4. In case the foreign site is not accredited by the NAB, RvA's policy rule RvA-BR005 applies for the frequency and extent of the assessments.

Article 14.

The frequency and extent of assessments of foreign sites which are considered to be sites with no key activities are based on the rules in RvA-BR005. In addition to the aspects as stated in RvA-BR005, the following aspects are considered in determining the frequency and extent of the assessment. In order to gather input on these aspects, the RvA could ask the NAB for support.

- Knowledge of the local regulations and the local market
- Impact of the body on the local market

Article 15.

- For assessments of conformity assessment activities performed in other countries in the EA-MLA
 region and the subcontracting to or cooperation with the NAB, RvA will not need prior approval
 from or communication with the CAB, if the NAB is a signatory of the relevant EA MLA/BLA for
 the relevant conformity assessment activity.
- Also RvA will not need prior approval from or communication with the CAB to share relevant information with such a NAB concerning the CAB.
- The RvA will inform the relevant NAB's of any decision to suspend or withdraw accreditation for an acredited activity performed in the foreign site.

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Article 16.

For the purpose of planning of subcontracted assessments RvA will inform the NABs in the EA-MLA region before October of each year about the plans for subcontracted assessments in the following year. At this stage, the exact extent of the assessment may not be clear but such early information is essential to allow for resource planning by the NAB. The extent of the assessment will have to be reported to the respective NAB's preferably at the latest three months before the due date of the assessment. The RvA will inform respective NABs in the EA-MLA region about any request made (e.g. regarding ad-hoc assessments or extensions to scope) as soon as such request is known.

4. Conducting subcontracted assessments for NABs in the EA MLA region

Article 17.

When requested by the NAB of a country in the EA-MLA region, RvA will act as a subcontractor for assessments of CABs in the Netherlands, provided RvA has the resources to do so, in the following situations:

- A CAB registered in the Netherlands operates as a site under the accredited scope of a foreign CAB, accredited by the NAB of the country in which this CAB is registered.
- 2. A foreign CAB accredited by the NAB of the country in which this CAB is registered, conducts conformity assessment activities which the NAB wants to be assessed in the Netherlands.

Article 18.

When acting as subcontractor RvA will use its own procedures. Reports will be provided to the subcontracting NAB within the timeframe specified in the agreement with the foreign AB. The RvA will inform the subcontracting AB as soon as possible about findings classified as category A nonconformities (following policy rule RvA-BR004).

5. RvA accreditation outside the EA-MLA region

Article 19.

For accreditation outside the EA-MLA the following policy applies:

- The RvA will only consider providing accreditation to CAB's that are registered in countries
 outside the EA-MLA region in case accreditation is requested for conformity assessment activities
 that cannot be accredited locally or for which a secondary accreditation is desired next to a local
 accreditation.
- CAB's registered in countries outside the EA-MLA region that apply for accreditation by the RvA
 will firstly be referred to a local AB or, in case there is no local AB, to an AB in the region where
 such CAB is registered.
- Secondary accreditation is only considered in case a desired RvA-scope demonstrably matches the scope of a local accreditation.

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4. Before accepting any application for accreditation by a CAB registered outside the EA-MLA region, the RvA will evaluate the reasons why the CAB is applying for accreditation outside its country of establishment.

Article 20.

The following specific rules apply for assessments of CABs registered in countries outside the EA-MLA region and for cooperation with local AB's:

- If an application is accepted by the RvA, the RvA will inform any relevant local AB about the
 application, including the specific accreditation scope, and seek advice on possible accreditation
 constraints.
- 2. If a requested scope is part of the IAF-MLA or ILAC-MRA scope of a local AB, the RvA will conduct joint assessments with this local AB.
- If a requested scope is not part of the IAF-MLA or ILAC-MRA scope of a local AB, the RvA will
 conduct its own assessment. In this case, the RvA aims to cooperate with a local AB where
 possible and include local and regional experts in its team where necessary.
- 4. The RvA Executive Board may decide to conduct assessments independently from other accreditation bodies. The local AB will always be informed about the reasons for such a decision.
- The frequency and extent of the assessments will in all cases be consistent with the rules of RvA (RvA-BR005).

Article 21.

For each accreditation granted according to the rules in this chapter the RvA will reconsider the validity of the justification for foreign accreditations at least every four years. If the justification is no longer valid RvA will not initiate a new accreditation cycle or extend an accreditation. The RvA will support the transfer of the accreditation to another AB before renewal where possible and when requested by the CAB.

6. Assessments of foreign sites and activities outside the EA-MLA region

Article 22.

The RvA will subcontract assessments at foreign sites not being the head office of the RvA accredited CAB to the local AB if this AB is an ILAC-MRA or IAF-MLA signatory for the activities to be accredited. For such subcontracting the rules explained in chapter 7 apply. If the local AB is not a signatory to a relevant MLA/MRA, the assessment will be performed by the RvA. In this case, if possible, the RvA will include assessors and/or experts from the local, or another, AB in its team.

Article 23.

An assessment at a new site to be added to the list of sites where key activities are carried out (see RvA-BR003 for the definition of key activities) will be conducted by an RvA assessment team; if necessary local or regional experts will be included in this team.

Article 24.

The witnessing of activities (for example on-site testing, audits, inspections) that Dutch CABs conduct outside the EA-MLA region, by staff directly controlled by the Dutch office of the CAB, will preferably be carried out by RvA assessors. The RvA will however use local experts when relevant for the competence of the RvA assessment team.

Article 25.

The frequency and extent of the assessments at sites of a RvA accredited CAB will be consistent with the rules as explained in RvA-BR005.

7. Subcontracting to and cooperation with other Accreditation Bodies

Article 26.

Cooperation with other accreditation bodies may consist of:

- 1. Assessment personnel recruited from the other AB are part of the RvA assessment team. If this AB is not a signatory to a relevant MLA/MRA, the RvA is responsible for training, qualification and monitoring of this assessor or expert. If this AB is a signatory to a relevant MLA/MRA, the RvA will qualify the person for a specific task based on the competence information provided by the other AB:
- 2. A joint assessment by the RvA and the other AB. The team is composed of assessors/experts from both ABs. Further implementation of this cooperation requires deliberation with regard to reporting, procedures, costs and responsibilities on a case by case bases. A formal agreement dealing with these issues may be drawn up between the RvA and the other AB;
- 3. Subcontracting an assessment. See Article 27 and further.
- 4. Conducting subcontracted assessments for other ABs. See <u>chapter 4</u>.
- 5. A local AB observing the RvA assessments in its country. RvA will support local ABs to observe RvA assessments.

Article 27.

The following policies apply in the event of subcontracting:

- 1. Where the RvA subcontracts assessments, clause 6.4 (outsourcing) of ISO/IEC 17011 applies.
- 2. When the RvA contracts another AB to conduct assessment on its behalf, the other AB will use its own accreditation assessment procedures, systems and reports and will not be required to use the assessment procedures of the RvA.
- 3. The RvA is however entitled to specify particular areas or aspects of the assessment on which it requires the other AB to focus the assessment and the reporting. The other AB shall ensure that it meets the requirements of the RvA in such matters. The RvA will provide the other AB with all the information needed to ensure an effective assessment.

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- 4. The language to be used during the assessment shall be agreed upon between the contracted AB and the CAB in advance of the assessment. The language of the reports provided to the RvA shall be English or Dutch.
- 5. The costs of the assessment may be invoiced to the CAB by the contracted AB direct, in which case the RvA will invoice the CAB an additional administrative fee to cover the costs of subcontracting.
- 6. A subcontracting agreement with the other AB will be drafted to specify the detailed terms and conditions.

Article 28.

The information provided to the subcontracted AB in case of subcontracted assessments includes, but may not be limited to:

- 1. Report of the last head office assessment.
- 2. Up-to-date information about the CAB including details of how it is organised and managed and how the conformity assessment activities carried out at/from its locations are controlled
- 3. Assessment specification in which any specific additional requirements or activities to be particularly assessed by the subcontracted AB are included.
- 4. Any requirements from regulators which may have an impact on the activities of the foreign site when accreditation is being granted for the purposes of notification.
- 5. Full scope of the activities which can be performed by the local site under the multi site accreditation.
- 6. Detailed description of the scope to be assessed, including any sector specific schemes.
- 7. Assessment plan, including plan for witnessing, for the site over the full accreditation cycle.

Article 29.

The decision making in case of subcontracted assessments follows the following principles:

- 1. In case the site of the CAB is also accredited for the same or a larger scope, then the RvA will receive the report within the time frame agreed with the subcontracted AB. However in the event the assessment revealed a finding which RvA would classify as a category A nonconformity then the subcontracted AB will inform RvA immediately after the closing meeting of the assessment at this site. RvA will on a case-by-case bases decide on the actions to be initiated in those situations.
- 2. In case the site of the CAB is accredited by the subcontracted AB for only part of the scope of RvA's accreditation or is not accredited at all, then the results of the assessments are provided to the RvA as soon as possible.
- 3. Because a finding at each site of an RvA accredited CAB is considered a finding for which the head office of the RvA accredited CAB is responsible, RvA will decide on the follow-up and closing of such findings.

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- 4. In case RvA requires an on-site assessment for the follow-up of findings at foreign sites, RvA will subcontract this assessment to the subcontracted AB and receive the report on findings within the agreed time frame.
- The RvA always remains responsible for the decision making based on the report provided by the NAB. The RvA will inform the subcontracted AB about decisions based on the subcontracted assessment.

Article 30.

RvA will exchange all relevant information with foreign AB's about CABs accredited by those AB's.

This information may concern complaints and other information related to the performance of the CAB.

Article 31.

In the event that the RvA suspends or withdraws an accreditation of a CAB that also holds an accreditation from the local AB, the RvA will inform this local AB accordingly. Any other AB having accredited the CAB will also be informed, provided this accreditation is included in the IAF accreditations database or the RvA has other means of obtaining this information.

Article 32.

Whenever the RvA is informed about the suspension or withdrawal of an accreditation by another AB for a CAB that also holds an RvA accreditation, the RvA will carry out an investigation. The purpose of this investigation is to decide whether the grounds for suspension or withdrawal necessarily have an impact on RvA's accreditation of this CAB. RvA will inform the other AB of the outcome of this investigation.

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Appendix: Overview of changes compared with Policy rule for Cross Frontier Accreditation (version 2, July 2013)

This Policy rule for cross border accreditation succeeds the Policy rule for Cross Frontier Accreditation. In comparison to the Policy rule for Cross Frontier Accreditation, significant changes are:

- Articles related to RvA accreditation and assessments in foreign countries within the EA-MLA region have been modified to match the policy as outlined in EA-2/13. Policy changes include:
- The addition of articles regarding the cooperation and information provision between the RvA and other ABs (in <u>articles 10</u> and <u>28</u>).
- Changing the fact that the conditions of the Regulation (EC) No. 765/2008 are checked (in <u>article</u> 10) at the end of the accreditation cycle and in case of an extension.
- The addition of criteria on the basis of which the RvA may select sites with no key activities (in article 14) for its assessments.
- A more detailed description of cooperation with local AB's and coordination regarding cross border activities relating to foreign regulations (in line with EA-2/13, articles 1, 3, 7, 8 and 10)
- Article 12 has (also) been amended in line with EA-2/13. Witnessing within the EA-MLA region outside the Netherlands shall be subcontracted to a local NAB.
- Article 8, regarding information provision with respect to locations of activity has been withdrawn.

 Requirements regarding information provision will be described in policy rule RvA-BR005 instead.
- The policy for 'RvA accreditation outside the EA-MLA region' has been set out more clearly.
 Chapter 5 has been rewritten for this purpose.
- In <u>Articles 13</u>, <u>14</u> and <u>23</u>, the term critical location has been changed to site with key activities in line with RvA Policy Rule RvA-BR003.
- References to expired transition periods for past policy changes have been deleted in this version.

Due to the addition and rejection of articles, the articles in this Policy rule for cross border accreditation cannot be compared by number with the articles the Policy rule for Cross Frontier Accreditation.

Version 2 of the Policy Rule for Cross Frontier Accreditation of 9 July 2013 is available on request.

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